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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/752,712	12/28/2000	James E. Parker	VTECH-48514	9398

7590

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EXAMINER

SIEFKE, SAMUEL P

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 05/17/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/752,712

Applicant(s)

PARKER, JAMES E.

Examiner

Samuel P Siefke

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims **1-14, 25-27,30,31** are rejected under 35 U.S.C. 102(e) as being anticipated by Tydings et al. (USPN 6,379,620).

Tydings '969 discloses an assay device for urine analysis comprising:

- a container having interior chamber with a liquid sample space, a plurality of assay strips disposed in the interior chamber, a separator disposed between the interior chamber and the assay strips, a wick means disposed in the interior chamber in fluid communication with assay strips, each assay strip comprises wicking material for conducting the liquid sample from the wick to the assay region of the assay strip (col. 2, lines 30-67; claim 1-3);
- a pair of ribs on the interior surface, forming a slot for receiving and retaining the assay strip and wick (col. 3, lines 4-6);
- a cap is provided for closing and sealing the container (col. 2, lines 30-45);

- a separator member is disposed in the interior chamber separating the liquid sample space from the assay region of the assay strip (col. 2, lines 37-45), a bridging wick piece (reagent strip) being in fluid communication with the wick and in immediate contact with the assay strip for conducting the liquid sample from the wick to the assay strip (col. 2, lines 65-67);
- a retainer member disposed over the assay strip and wick for retaining the assay strip and wick in place in the interior chamber (col. 3, lines 6-10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims **15-24, 28,29** are rejected under 35 U.S.C. 103(a) as being unpatentable over Tydings et al. (USPN 6,379,620).

Tydings '969 discloses an assay device for urine analysis comprising:

- a transparent container having interior chamber with a liquid sample space, a plurality of assay strips disposed in the interior chamber, a separator disposed between the interior chamber and the assay strips, a wick means disposed in the interior chamber in fluid communication with assay strips, each assay strip comprises wicking material for conducting the liquid sample from the wick to the assay region of the assay strip (col. 2, lines 30-67; claim 1-3);
- a pair of ribs on the interior surface, forming a slot for receiving and retaining the assay strip and wick (col. 3, lines 4-6);
- a transparent cap is provided for closing and sealing the container (col. 2, lines 30-45);
- a separator member is disposed in the interior chamber separating the liquid sample space from the assay region of the assay strip (col. 2, lines 37-45), a bridging wick piece (reagent strip) being in fluid communication with the wick and in immediate contact with the assay strip for conducting the liquid sample from the wick to the assay strip (col. 2, lines 65-67);
- a retainer member disposed over the assay strip and wick for retaining the assay strip and wick in place in the interior chamber (col. 3, lines 6-10).

Tydings is silent on subject matter regarding the wicking material being mounted to the cap and extending into the liquid sample space. This is a common technique to use for assay testing because in order to remove the assay test from the sample container without any contamination of the test strips one ordinarily provides the tests strips being

attached to the cap for easy removal after testing is complete. This would have been obvious to one having an ordinary skill in the art to provide the wicking material and the assay test strips as one with the cap in order to allow for a contamination free procedure.

Tydings is also silent regarding the collection vial being a protective mailing tube. This would have been obvious to one having an ordinary skill in the art at the time the invention was made to modify the container of Tydings to be made of a protective material that would keep the assay in tact for mailing purposes. The assay would be mailed in order to transfer test results to a laboratory or a doctor for patient screening, therefore then tube would have to be made to protect the assay result from being tampered with or destroyed in transport.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P Siefke whose telephone number is 703-306-0093. The examiner can normally be reached on M-F 7:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers


Art Unit: 1743

for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

SPS
May 14, 2002




Bill Warden
Supervisory Patent Examiner
Technology Center 1700